NOV 18 2004

K042076

510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

July 29, 2004 [Amended 10/27/04]

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o Fujinon Inc.
543 Long Hill Avenue
Shelton, CT. 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor Fujinon Inc., 10 High Point Drive, Wayne, NJ 07470, Establishment Registration# 2431293.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are: Fujinon G5 Duodenoscopes

Common Name: Duodenoscopes

Classification: Class II, 21 CFR 876.1500, FAK

Predicate Device [21 CFR 807.92(a)(3)]

- Fujinon ED-400XL – K944620
- Fujinon ED-200XU – K944759

The G5 changes were described and cleared by FDA in the 510(k) submission for the Fujinon Double Balloon Enteroscopy System – K040048.

This 510(k) captures some minor design changes that have occurred during the evolution of the product line resulting in the G5 family of scopes. Although the changes are believed to be minor, the 510(k) is being submitted to account for "design creep" and to ensure that FDA has the most current information concerning the Fujinon Duodenoscopes.

The subject devices have the **same** indications for use, composition of patient contact materials, viewing direction, length, and reprocessing/sterilization method as the predicates. The subject devices use the same processors and peripherals as the predicate device.

The main differences between the subject devices and predicate devices are as follows:

- Minor differences with observation range, field of view, diameter, and bending capacity.
- The subject device includes the G5 upgrade, which is characterized by the following minor differences:
    - The L-Port has been eliminated. The L-port functioned as a lens wash port . Doctors had the option to take a syringe to inject a fluid to use it as a high pressure wash for the lens.

This function was eliminated because demand was low and it was rarely used by the surgeons.

- A G5 forceps inlet port was modified. The new port is smaller and comes with a rubber cap. The smaller port and rubber cap help increase suction and reduce leakage.
- The jet wash line check valve was removed. Internal check valves were removed to eliminate the potential for clogging and to facilitate cleaning, disinfection, and sterilization. The valves are now external and removable.
- The suction and air/water cylinders and valves were upgraded. They were updated to accommodate the new valves. The function of the valves is the same.
- Addition of the FOV, which is the rubber forceps inlet valve cover. This helps create a watertight seal when the endoscope is used.
- Upgrade to CA-500 cleaning adaptor. The cleaning adaptor allows the scope to be connected to tubes for cleaning.

Description of the Device [21 CFR 807.92(a)(4)]

The Fujinon G5 Duodenoscopes are medical endoscopes used for the visualization of the duodenum and upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

The G5 Duodenoscopes are offered in a 200 and 400 series. The ED-250XT5 represents the G5 Duodenoscope 200 series and the ED-450XT5 represents the G5 Duodenoscope 400 series.

The G5 Duodenoscopes include minor changes that improve the useability, ergonomics, and cleaning of the devices. The G5 scopes do not have an L-Port. The L-port functioned as a lens wash port. Doctors had the option to take a syringe to inject a fluid to use it as a high pressure wash for the lens. This function was eliminated because demand was low and it was rarely used by the surgeons.

A G5 forceps inlet port was modified. The new port is smaller and comes with a rubber cap. The new design helps increase suction and reduces leakage.

The jet wash line check valve was removed. Internal check valves were removed to eliminate the potential for clogging and to facilitate cleaning, disinfection, and sterilization. The valves are now external and removable.

The suction and air/water cylinders and valves were upgraded. They were updated to accommodate the new valves. The function of the valves is the same.

The G5 Duodenoscopes also feature the addition of the FOV, which is the rubber forceps inlet valve cover. This helps create a watertight seal when the endoscope is used. Upgrade to CA-500 cleaning adaptor. The cleaning adaptor allows the scope to be connected to tubes for cleaning.

The G5 Duodenoscopes are used with the same processors, monitors, hard copy units, and carts as the predicate devices. Each Duodenoscope is packaged in a protective carrying case with lens cleaner, silicon oil, forceps valve, waterproof cap, S connector cap, protective cap, adapters, valves, and the Operation Manual.

The Fujinon G5 Duodenoscopes are used in conjunction with other peripherals specified in the Operation Manual such as:

- Light Source

- Processor
- Cart
- Data Keyboard
- Foot Switch
- Monitor
- Video Printer
- Camera and Hard Copy Unit
- VCR
- ElectroSurgical Instruments

Specifications for ED-450XT5 and ED-250XT5

	ED-450XT5	ED-250XT5
Viewing Direction	Lateral (15 degrees retro)	Lateral (15 degrees retro)
Observation Range	3-60mm	5-60mm
Field of View	100 degrees	100 degrees
Image Size	Super Image	Super Image
Distal End Diameter	13.5mm	13.5mm
Flexible Portion Diameter	12.6mm	12.6mm
Bending Capacity UP	130 degrees	130 degrees
Bending Capacity DOWN	90 degrees	90 degrees
Bending Capacity LEFT	90 degrees	90 degrees
Bending Capacity RIGHT	110 degrees	110 degrees
Forceps Channel Diameter	4.2mm	4.2mm
Working Length	1250mm	1250mm
Total Length	1550mm	1550mm

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		ED-450XT5	ED-250XT5
Material of Outer Lines (G1)		LaSf-n17	LaSf-n17
Lens Diameter (mm)		2.2	2.2
Electronic Video Imaging System	Total Pixels	411,988	411,988
	Pixels per square millimeter	83,892	83,892
	Size of Pixel (H*V mm)	0.0032*0.003725	0.0032*0.003725
	Active area of CCD chip (H*V mm)	2.458*1.840	2.458*1.840
	Type of CCD chip	Interline Color Chip	Interline Color Chip
Image Quality Resolution (lines / mm) – Near Point		15.9 lines/mm (6mm)	14.3 lines/mm (7mm)
Image Quality Resolution (lines/mm) – Far Point		2.00 lines/mm (60mm)	1.59 lines/mm (60mm)
Magnification (specify monitor size and type used for this specification)		26 (5m) at 14 inch monitor	31 (5m) at 14 inch monitor
Focal Length		1.459mm	1.459mm

Intended Use [21 CFR 807.92(a)(5)]

The device is intended for the visualization of the duodenum and upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

Technological Characteristics [21 CFR 807.92(a)(6)]

Fujinon, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device have the **same** indications for use, composition of patient contact material, viewing direction, length, and reprocessing/sterilization method as the predicate. The subject devices use the same processors and peripherals as the predicate devices.

The main differences are the minor changes associated with the G5 upgrade. The G5 changes were previously cleared by FDA in the 510(k) submission for the Fujinon Double Balloon Enteroscopy System – K040048.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed EMC testing requirements. The patient contact materials in the Duodenoscopes are identical to the materials used in the predicate device.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 2004

Fujinon, Inc.
c/o Mr. Joseph M. Azary
Azary Technologies™ LLC
543 Long Hill Avenue
SHELTON CT 06484

Re: K042076
Trade/Device Name: G5 Duodenoscopes
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FDT
Dated: October 27, 2004
Received: October 28, 2004

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K042076

510(k) Number (if known): K042076

Device Name: Fujinon Inc. G5 Duodenoscopes

The device is intended for the visualization of the duodenum and upper digestive tract, specifically for the observation, diagnosis, and endoscopic treatment of the esophagus, stomach, and duodenum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Hegarty
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042076